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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,207	08/17/2005	Thibaut Jose Wenzel	GRT/4662-46	8474
23117 7590 11/27/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 11/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,207	Applicant(s) WENZEL ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/18/05</u> | 6) <input type="checkbox"/> Other: _____ |

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The case is the national stage of the PCT/EP2004/00173. Response to restriction and amendment filed Oct. 5, 2007 are acknowledged. Claims 1-11 have been amended, and new claims 12-18 have been added. Applicants elected group I, claims 1-8 and 11-16. These claims are under examination. Claims 9-10 and 17-18 are withdrawn from examiner's consideration as directed to a non-elected invention.

DETAILED ACTION

Restriction/election

Applicant's election without traverse of group I, claims 1-8 and 11-16 in the reply filed on Oct. 5, 2007 is acknowledged. Applicants, however, requested rejoinder of nonelected method claims upon an indication that an elected product claim is allowable. This request is noted by the examiner.

Priority

Applicants claim of benefits of EPO patent application 03100236.3 filed May 2, 2003 has been noted. Because the certified copy of this document has been filled and the subject matter of the claims under examination is comprised in the priority document, the priority of the instant claims to the EPO application has been granted.

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Objections

Please expand the abbreviations OAH and MTP when used for the first time in the specification, and provide the abbreviation in parenthesis after the full names.

In claim 5 the article before "heterologous" should be "a".

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

Rejections

35 USC 112 first paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected 1-8 and 11-16 as confusing.

Claim 1 is confusing in recitation "originated from a wild type strain for production of an enzyme". The mutants obtained by applicants are originating from a wild type but they were obtained to be oxalate deficient, and not to produce an enzyme.

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Claims 1-8 and 11-16 are confusing in the light of the disclosure, because the mutants of WT2 cells are compared with wild type WT1 that was not mutated.

Particularly, Claim 7 is rejected, because the mutant claimed in claim 7 originates from WT2 cells that were obtained by Wrisel et al, 1998, and contain an expression cassette comprising several copies of alpha-amylase of *A. oryzae* integrated into their genome. Applicants state on page 14, line 5 of the specification that the wild type *A. niger* CBA 513.88, i.e. WT1 is used as a control for the level of oxalate, given enzyme and intracellular OAH activity. WT1 as such does not produce any alpha amylase and was not irradiated with UV, i.e., applicants do not disclose UV mutated CBA 513.88. Thus CBA 513.88 it is not a proper control in the claimed invention. The WT2 mutant containing more amylase than WT2 itself cannot be compared with WT1 wild type that does not possess amylase activity at all.

Claims 13-16 are rejected because it is not clear to what "at least 15 mM " and "at least 30 mM " they refer to.

35 USC 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an oxalate deficient A. niger strain for production of any enzyme, wherein the enzyme production is at least the same as that produced by the wild type as well as to the method of producing such strain and for the use of said strain for production of any enzyme/fungal amylase, and to a method of using said A. niger strain for production of an enzyme.

The claims are lacking sufficient written description of the claimed oxalate deficient A. niger strain, because although the claims state that the mutated strain is deficient in oxalate production this only feature does not identify the claimed strain. The art at the time of invention knew several A. niger mutants that do not produce oxalate and one having skills in the art realizes that UV mutagenesis applied by Applicants to obtain the strain leads to plethora of changes in enzyme production by the mutated cell in addition to deficiency in oxalate production. Thus, as long as an UV mutant is it may be always used for production of enzymes, and certainly there exists at least one enzyme in the whole metabolism of the mutant that is produced at "at least the same level" as in the wild type. The scope of the claims is in addition broadened by the fact that applicants themselves use two A. niger strain that they called "wild", and the art knows many A. niger strains that are used as a wild type.

The claimed mutated strain is characterized by

- 1) deficiency of oxalate production, and

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- 2) at least the same production of an enzyme having any possible activity and being endogenous or recombinantly expressed in said mutated strain.

Thus the claims are directed to an extremely large genus of *A. niger* strains which is lacking sufficient identification. The disclosure teaches the UV mutants of *A. niger* that are oxalate deficient and as host cells recombinantly express more proline specific endoprotease and phospholipase A1 than wild type. These mutants, however, do not identify the whole, astronomically large genus of mutants toward which the claims are directed. All claims are rejected as lacking written description of the proper control i.e. wild type for comparison the effects of oxalate deficiency. The oxalate deficient cells are obtained from WT2 control and the effects of oxalate deficiency on enzyme production compared with WT1 wild type from which the mutated cells do not originate.

In conclusion, one skilled in the art is not convinced that Applicants were in possession of the claimed invention at the time the application was filed.

35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen et al. (Construction and Characterization of an Oxalic Acid Nonproducing Strain of *Aspergillus niger*, Metabolic Engineering, 2000, 2, 34-41); enclosed in the IDS.

The claims are directed to an oxalate deficient *A. niger* mutant strain producing at least the same amount of an enzyme as the wild type under the same culture condition.

Pedersen et al. disrupted the *oah* gene of *A. niger*, producing an oxalate deficient mutant. They characterized basic metabolism of said mutant; see page 38, Table. 1. The disrupted mutant synthesized aspartate and threonine in the level not lower than in the wild type and more glycine than in the wild type. This means that at least one of the enzymes involved in synthesis of aspartate, threonine and glycine was synthesized by mutant at the level higher than in the wild type.

Pedersen anticipates the invention as claimed in claims 1, 2.

In addition, claims 4-5, 7-8 and 11 are rejected under this paragraph as anticipated by WO 00/50576 published Aug. 31 2000. The document teaches *Aspergillus niger* strains mutated by disrupting the *oah* gene transfected for recombinant production of many enzymes, for the purpose of industrial and laboratory production. Among the enzymes they listed any alpha amylase. See pages 34, 35, 37 and claims 14, 15, 23, 25, 26.

Conclusion

All claims are rejected.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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